I. Medication Description

Darolutamide is an androgen receptor (AR) antagonist with a distinct structure that offers the potential for fewer and less severe toxic effects because of its low penetration of the blood-brain barrier and low binding affinity for gamma-aminobutyric acid type A (GABAA) receptors. The androgen-AR signaling pathway is important in castration-resistant prostate cancer (CRPC). Darolutamide competitively inhibits androgen binding, AR nuclear translocation, and AR-mediated transcription. In addition, darolutamide also blocks the activity of mutant androgen receptors that arise in response to antiandrogen therapies, which confer resistance to other androgen receptor antagonists.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Nubeqa is available when the following criteria have been met:

- Member is at least 18 years of age AND
- The medication is prescribed by a hematologist, oncologist, or urologist AND
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

IV. Quantity Limitations

Coverage is provided as follows:

- 300mg tablets: up to 120 tablets per 30 days

V. Coverage Duration

Coverage is provided for 6 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Stabilization of disease or in absence of disease progression AND
• Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

Available as 300mg oral tablets

VIII. Summary of Policy Changes

• 10/15/19: new policy

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.